IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC., *Plaintiff,* v. DAIICHI SANKYO CO., LTD., *Defendant, and* ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA UK LTD., *Intervenor-Defendants*	)	CASE NO. 2:20-cv-00337-JRG [redacted]

DEFENDANT DAIICHI SANKYO COMPANY, LIMITED AND INTERVENOR-DEFENDANTS' ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA UK LTD.'S
MOTION FOR SUMMARY JUDGMENT OF ANTICIPATION

TABLE OF CONTENTS

CASES

STATUTES

RULES

OTHER

I. INTRODUCTION

Claim 1 recites a group, or "genus," of antibody-drug conjugates. One critical feature of the claim concerns the "linker" that connects the drug to the antibody. Claim 1 requires that the linker comprise a "tetrapeptide" (a chain of four amino acids) that consists *only* of two particular amino acids: glycine and phenylalanine.

But the claimed "Gly/Phe-only" tetrapeptide linkers are nowhere disclosed in the asserted patent or the applications to which it claims priority. None of the patent's ADC examples contain a Gly/Phe-only tetrapeptide. The concept is mentioned nowhere in the patent's disclosure or in the 2003 or 2004 priority applications (collectively the "Priority Applications").[1] In 2019, years after filing those applications, and years after first learning of an ADC with a Gly/Phe-only tetrapeptide by attending a Daiichi Sankyo Company ("DSC") presentation regarding DS-8201, Seagen filed a new, continuation application that claimed ADCs comprising what its *own scientists* called "Daiichi-Sankyo's drug-linker"—a Gly/Phe-only tetrapeptide. SGIEDTX00164812 (Ex. 1) at 815. That application became asserted U.S. Patent No. 10,808,039 (the "'039 patent").

Patent law does not countenance claiming the inventions of others. The written description requirement of § 112 prevents an inventor "from later asserting that he invented that which he did not." *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009). A patentee may claim priority to the filing date of an earlier-filed application only if it describes the later-claimed invention in a way that demonstrates the inventors were in possession of that invention at the earlier time. This "written description requirement is particularly important when, as here,

[1] The "2003 Application" refers to U.S. Provisional Patent Application No. 60/518,534, and the "2004 Application" refers to U.S. Patent Application No. 10/983,340.

claims are added later during prosecution in response to development by others." *FWP IP ApS v. Biogen MA, Inc.*, 749 F. App'x 969, 974 (Fed. Cir. 2018).

The '039 patent's utter lack disclosure of ADCs with a Gly/Phe-only tetrapeptide is plain. Indeed, Seagen does not even try to identify any support within its own patent or "Priority Applications" for this particular subgenus of tetrapeptides. There is no dispute that the applications provide no examples of an ADC with a Gly/Phe-only tetrapeptide. Nor is there any dispute that, at the time they filed either of the Priority Applications, the inventors had not made or even thought of an ADC with a Gly/Phe-only tetrapeptide—a proposition that forecloses a claim to priority as a matter of logic and controlling law, because "[o]ne cannot describe what one has not conceived." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1367 n.13 (Fed. Cir. 2006) (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

Despite the admitted lack of actual possession of the claimed tetrapeptide or any specific disclosure of it in the Priority Applications, Seagen nonetheless contends that it is entitled to claim priority because its earlier applications broadly disclosed using linkers having between two and twelve amino acids, with any of 83 amino acids at each of the two to twelve positions. Thus, according to Seagen, the Priority Applications described each of the unfathomably large number of sequences that fall within that disclosure. But this runs headlong into a clear and consistent line of Federal Circuit authority rejecting conclusively the possibility that such a "'laundry list' disclosure of every possibly moiety for every possible position would constitute a written description of every species in the genus." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996). Where, as here, the earlier-filed "priority" application broadly discloses a genus, and the later-filed patent claims only a partial "subgenus" of that disclosure, the priority application must include "blaze marks" directing the person of ordinary skill ("POSA") to the narrower, later-

claimed subgenus. Seagen has not identified any such "blaze marks" in its Priority Applications. Rather, Seagen resorts to identifying blaze marks that, Seagen does not dispute, point to at least three subgenera *other* than the one it claimed in the '039 patent.

The consequence of Seagen's inability to claim priority is undisputed. Seagen agrees that, without a successful claim to a Priority Application, the Asserted Claims (1-5, 9-10) are anticipated by Daiichi Sankyo Japan's 2016 publication of DS-8201 by Ogitani[2]—and thus invalid. To succeed on its infringement claims, it must demonstrate that DS-8201 meets every limitation of the Asserted Claims. *See Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 842 (Fed. Cir. 1999). But "[t]hat which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889). Accordingly, if the Asserted Claims cannot claim priority back to the early 2003-2004, then they are anticipated by disclosures of DS-8201 if, as Seagen alleges, it infringes. Seagen cannot—and does not— argue otherwise, lest it plead itself out of an infringement case.

This motion for summary judgment of anticipation thus does not require a comparison of the prior art to the Asserted Claims. Instead, it turns on a different question: whether Seagen's broad 2003/2004 disclosure of using any of 83 amino acids in peptide linkers of any length can support its far narrower claims to ADCs with a Gly/Phe-only tetrapeptide. Controlling authority says "no" as a matter of law. The claims are therefore anticipated if Seagen's infringement theory is correct.

II. STATEMENT OF ISSUES TO BE DECIDED BY THE COURT

[2] Ogitani, Yusuke et al., *DS-8201a, A Novel HER2-Targeting ADC with a Novel DNA Topoisomerase I Inhibitor, Demonstrates a Promising Antitumor Efficacy with Differentiation from T-DM1*, 22 CLIN. CANCER RES. 5097 (2016), DSC_ENHERTU_00025303-315 ("Ogitani") (Ex. 2). Other anticipatory publications will be addressed if this case proceeds to trial, but are unnecessary for purposes of this motion since Seagen concedes Ogitani disclosed every limitation of the Asserted Claim.

Defendants' motion respectfully requests the Court decide the following issue:

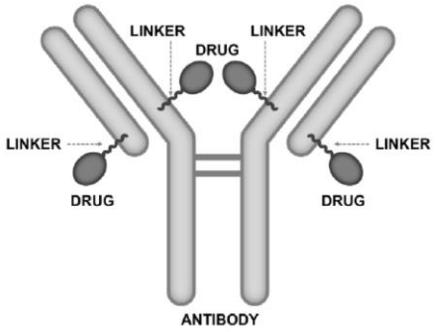
- The '039 patent is not entitled to a priority date before July 2019 and therefore is anticipated by Ogitani if Seagen's infringement theory is correct.

III. BACKGROUND AND STATEMENT OF UNDISPUTED MATERIAL FACTS

A. The '039 Patent

1. The Asserted Claims

The Asserted Claims claim antibody-drug conjugates ("ADCs") with particular structural features and function.[3] ADCs are complicated molecules designed to deliver potent chemotherapy to cancerous cells while sparing healthy ones. Bertozzi[4] Opening Rep. (Ex. 3) at ¶ 43; Lambert[5] Opening Rep. (Ex. 4) at ¶ 42. In particular, ADCs are composed of three principal components: (1) an antibody connected to (2) a drug moiety via (3) a linker. Bertozzi Opening Rep. at ¶ 42; Lambert Opening Rep. at ¶¶ 42-43.



The antibody targets cancer cells, bringing along with it the drug moiety that can kill the cancer cells after it is released from the antibody by cleavage of the connecting linker. Bertozzi Opening

[3] The Asserted Claims do not limit the drug that can be used in the ADC, pursuant to this Court's *Markman* order. Dkt. 155, at 15. Defendants dispute that the patent provides written description support for the use of any/all drugs in an ADC but that dispute is not the subject of this motion.

[4] Dr. Bertozzi submitted expert reports on behalf of Seagen.

[5] Dr. Lambert submitted expert reports on behalf of Defendants and Intervenor-Defendants.

Rep. at ¶ 43, 56; Lambert Opening Rep. at ¶ 52. Linkers in ADCs can include "peptides"—i.e., chains of amino acids of various lengths; these are called "peptide linkers." Bertozzi Opening Rep. at ¶ 56, 58; Lambert Opening Rep. at ¶ 52.

The claimed ADCs have a small subset of one category of peptide linkers. Specifically, the Asserted Claims require *tetra*peptide linkers (i.e., the category with *four* amino acids in the chain) in which the only amino acids used are glycine or phenylalanine. Bertozzi Opening Rep. at ¶ 58; Lambert Opening Rep. at ¶ 120. This Motion refers to them as "G/F-only tetrapeptides."

Phenylalanine (abbreviated "Phe" or "F") is an amino acid that can occur in one of two configurations, called "isomers"—D-Phenylalanine or L-Phenylalanine. Glycine (abbreviated "Gly" or "G") can occur in only one isomer. The Asserted Claims do not require use of any particular isomer, and the parties therefore agree that there are 81 possible Gly/Phe-only tetrapeptides within the scope of the claims (three possible isomers at each of four positions, or three to the fourth power). Senter Dep. Tr.[6] (Ex. 5) 440:15-25; Lambert Opening Rep. ¶ 351.

2. The '039 Patent and Priority Applications Disclose 47 Million Linkers in the Tetrapeptide Category Alone

The '039 patent and the Priority Applications contain a general disclosure of eleven categories of peptide linkers, ranging from two amino acids long (dipeptides) to twelve amino acids long (dodecapeptides), and containing at each position any of 39 different amino acids. '039 patent (Ex. 6), 65:46-66:43; Bertozzi Rebuttal Rep. (Ex. 7) at ¶ 144; Lambert Opening Rep. at ¶ 347-49. Because all but one of those 39 amino acids can exist in two or three different configurations or "isomers," the parties agree that the '039 patent (and the identical disclosure in the 2004 application) discloses 83 options for each position in the amino acid linker chain.

[6] Dr. Senter, Seagen's Vice President of Chemistry, is a named inventor and Seagen's 30(b)(6) designee on conception of the claimed subject matter. Exs. 19-20.

Bertozzi Tr. (Ex. 8) 156:15-157:20; Lambert Opening Rep. at ¶ 350. Glycine and the two phenylalanine isomers are three among the 83 amino acids the patent discloses. They are not singled out. '039 patent, 65:55-66:43.

The result is an enormous number of possible peptide linkers. In the tetrapeptide category alone (setting aside the categories of 2-3 or 5-12 amino acid linkers), the parties agree the 2004 Application discloses over ***47 million*** linkers, and that is only one of many categories of peptide linkers disclosed. Senter Tr. 437:9-25 (30(b)(6) witness) ("Can you provide for me what the number of options that are disclosed just for the tetrapeptide category is in your patent? . . . A: You'll be so happy. It's over 47 million. . . . It's 47,458,321."); Bertozzi Tr. 156:15-157:20. Nothing in this broad disclosure points to the narrow subgenus of 81 Gly/Phe-only tetrapeptides. *Infra* Section V.B.

Seagen makes priority claims to two earlier applications filed in 2003 and 2004. The 2003 Application and 2004 Application differ only modestly in relevant part,[7] and there are no relevant differences between the 2004 Application and the '039 patent specification. Bertozzi Rebuttal Rep. ¶ 62-66, 293. All three applications disclose exemplary dipeptides, tripeptides and tetrapeptides. '039 patent (Ex. 6) at 66:47-68:12; 2003 Application (Ex. 9) at SGIEDTX000000857-59; 2004 Application (Ex. 10) at 86-87; [redacted]

From among the 47 million sequences covered by the tetrapeptide category alone, the 2004 application and the '039 patent disclose three examples of tetrapeptide linkers: glycine-phenylalanine-leucine-glycine; alanine-leucine-alanine-leucine; and glycine-serine-valine-

[7] *See, e.g.*, [redacted]

[8] Svetlana Doronina is a Seagen employee and the first named inventor of the '039 patent.

glutamine.[9] '039 patent, 67:45-50; 68:5-9. None of these is a Gly/Phe-only tetrapeptide, and none falls within the scope of the Asserted Claims. [redacted] Indeed, the applications do not recite or exemplify Gly/Phe-only peptides of *any* length. [redacted]

3. Seagen's Inventors Admit That They Were Not In Possession Of the Claimed Invention in 2003-2004.

The reason Seagen's inventors did not describe an ADC with a Gly/Phe-only tetrapeptide linker in their 2004 application is that [redacted] Seagen's inventors and its expert, Dr. Carolyn Bertozzi, admit that [redacted] Indeed, several of Seagen's named inventors testified that [redacted]

[9] The 2003 Application discloses only the first two examples; it does not include glycine-serine-valine-glutamine. SGIEDTX000000831 (Ex. 9) at 858-59.

[10] Dr. Scott Jeffrey is Seagen's Senior Director of Chemistry. Jeffrey Tr. 13:16-20.

[11] Dr. Stephen Alley is an Executive Director at Seagen and 30(b)(6) designee on topics including Seagen's knowledge of DS-8201 and the basis for its priority claim.

[12] Dr. Brian Toki is a Seagen employee and a named inventor on the '039 patent.

[redacted] Indeed, when Dr. Doronina was asked whether [redacted]

It was not until seven years later, on the eve of DS-8201's launch as Enhertu® in 2019, and well after Seagen had seen DS-8201's structure, that Seagen introduced the concept of Gly/Phe-only tetrapeptide linkers into its patent family *for the very first time*. It did so via the claims of the '839 Application, filed on July 10, 2019, and which issued as the '039 patent on October 20, 2020. Ex. 16 ('839 Application) at SGIEDTX00000404, 827-30; '039 patent, 331:50-63.

4. Seagen Identifies "Blaze Marks" to the Wrong Subgenera

Seagen suggests the Priority Applications contain blaze marks to the claimed invention because, Seagen alleges, the POSA would have been motivated to modify the examples disclosed in the Priority Applications, or synthesize wholly new peptide sequences, based on certain prior

art references.[13] [redacted]

Bertozzi Rebuttal Rep. at ¶¶ 174-177, 182.

Seagen identifies assorted information that it asserts would motivate the POSA who wished to modify the examples of the '039 patent. [redacted] Seagen asserts that this prior art—found nowhere in the Priority Applications—would have motivated the POSA to prepare additional sequences undisclosed in the Priority Applications but allegedly disclosed or suggested by the prior art, and thereby arrive at three new subgenera of peptide sequences. *See* [redacted]; Bertozzi Rebuttal Rep. at ¶¶ 174-77, 182. None of those three subgenera are recited in the Priority Applications.

Most importantly for purposes of this motion, Seagen agrees that none of those three subgenera is the Gly/Phe-only tetrapeptide subgenus claimed in the Asserted Claims. [redacted]. Each of these subgenera contains tetrapeptides using amino acids other than Glycine and Phenylalanine, and none of the subgenera contains all, most, or even many of the 81 claimed Gly/Phe-only tetrapeptides. [redacted]

[13] This approach is improper. Written description requires more than disclosure that "merely renders the invention obvious," *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc), and "proof of priority requires written description disclosure in the parent application, not simply information and inferences drawn from uncited references." *L. A. Biomedical Rsch. Inst. v. Eli Lilly & Co.*, 849 F.3d 1049, 1058 (Fed. Cir. 2017)*; infra* Section V.B.2.b.1.

B. DS-8201 Was Published Before Seagen's Patent Claims Were Filed and Therefore it Anticipates if, as Seagen Alleges, It Infringes

In March 2019, AstraZeneca and DSC announced a collaboration worth billions of dollars regarding the development and commercialization of DS-8201. Only months later, Seagen filed an application seeking to claim DS-8201, which matured into the asserted '039 patent. *See* '039 Patent (Ex. 6); Complaint ¶ 17 (Ex. 17); Bertozzi Opening Rep. at ¶ 55. Those patent claims were filed years after DS-8201 had been disclosed to the public as a promising new compound. *See* Ogitani (Ex. 2) (disclosing DS-8201's structure in 2016).

It is undisputed that unless the '039 patent is entitled to the early 2003-04 priority date Seagen claims, DS-8201 is prior art to the '039 patent. Bertozzi Rebuttal Rep. at ¶¶ 8, 321. To prove its infringement case, Seagen contends that DS-8201 meets every limitation of the Asserted Claims. *Id.* Thus, if the Asserted Claims lack priority to 2003-04, they are anticipated by DS-8201 if it infringes. Seagen does not argue otherwise. [redacted]; Bertozzi Rebuttal Rep. ¶ 321.

IV. LEGAL STANDARDS

Patents reflect a bargain: An inventor reaps the rewards of a temporary monopoly on her invention in exchange for disclosing that invention to the public. The public receives the benefit of this bargain only if the inventor *actually disclosed* the claimed invention. The various doctrines of patent validity—in particular, written description—exist to police this principle, preventing patentees from "looking at later developments and then claiming to have invented them when the initial application makes no mention of the subject matter." Michael Risch, *A Brief Defense of the Written Description Requirement*, 119 YALE L. J. 127, 130 (2010); *see also AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014). Seagen's predatory behavior seeks to flout this tenet of patent law by mining an extremely broad, general disclosure

of peptide linkers filed in 2003-2004 to claim an ADC using a very specific kind of peptide linker that the public did not receive until 2015 (and even then the public received it from DSC, not Seagen). The written description requirement was designed to prevent precisely this result. Seagen's Priority Applications do not disclose Gly/Phe-only tetrapeptide linkers, so the '039 patent cannot benefit from their filing date. DS-8201 is therefore prior art to the '039 patent and anticipates every asserted claim.

A. Summary Judgment

Summary judgment is appropriate when "there is no genuine dispute as to any material fact." Fed. R. Civ. P. 56(a). "At summary judgment, the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *D Three Enters., LLC v. SunModo Corp.*, 890 F.3d 1042, 1046 (Fed. Cir. 2018) (internal quotes omitted). Although compliance with the written description requirement is a "question of fact . . .[it] is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1361 (Fed. Cir. 2011).

B. Written Description

"It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995); 35 U.S.C. § 119. Section 112 provides in relevant part that "[t]he specification shall contain a written description of the invention." 35 U.S.C. § 112(a). To satisfy the written description requirement for purposes of priority, the earlier-filed application must "must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed" in the later-filed application, in order to "convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the [earlier] filing date." *Ariad*, 598

F. 3d at 1351. Adequate written description "requires a precise definition," *id.* at 1350; "[a] mere wish or plan to obtain the claimed invention is not sufficient." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011).

When an earlier-filed application discloses a broad genus but the later-filed application claims a species or narrower subgenus from within that disclosure, courts apply a "blaze marks" analysis. *Bos. Sci. Corp*, 647 F.3d at 1367. "[S]imply describing a large genus of compounds is *not sufficient* to satisfy the written description requirement as to particular species or sub-genuses." *Fujikawa*, 93 F.3d at 1571 (emphasis added). Otherwise, "a 'laundry list' disclosure of every possible moiety for every possible position would constitute a written description of every species in the genus," and "[t]his cannot be" the case. *Id.* Instead, the specification must contain "blaze marks" directing the POSA through the "forest" of the broad disclosure to the "particular trees" that constitute the claimed subgenus. *Application of Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967); *Fujikawa*, 93 F.3d at 1571. In the words of the Federal Circuit's predecessor:

> It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared— or have not yet been made, which is more like the case here— to be confronted simply by a large number of unmarked trees.…We are looking for blaze marks which single out particular trees. We see none.

Ruschig, 379 F.2d at 995. Blaze marks must indicate "what compounds, other than those disclosed as preferred, might of special interest." *Fujikawa*, 93 F.3d at 1571. Examples—a type of blaze mark—that are "close by" a later-claimed tree or set of trees are therefore legally insufficient, as they must "direct one *to the proposed tree in particular*." *Id.* (emphasis added).

For a claim to priority, "the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326-27 (Fed. Cir. 2000). Where, as here, a patentee adds claims in response to development by others, the written description requirement is particularly vital to enforce strictly, as it serves as the lone

bulwark against a patentee "later asserting that he invented that which he did not . . ." *FWP IP ApS*, 749 F. App'x at 974 (quoting *Agilent*, 567 F.3d at 1383). Courts frequently adjudicate non-compliance with the written description requirement as a matter of law. *See, e.g., Idenix Pharms., LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1163-64 (Fed. Cir. 2019) (reversing denial of judgment as a matter of law on written description); *Novozymes A/S v. DuPont Nutrition Bioscis. APS.*, 723 F.3d 1336, 1348 n. 5 (Fed. Cir. 2013) ("[A] verdict on written description is no more immune from review than any other factual issue, and we have in past cases held that the entry of judgment as a matter of law on written description grounds was appropriate."); *Bos. Sci. Corp.*, 647 F.3d at 1361 ("Compliance with the written description requirement . . . is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party.") (quoting *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008).

The written description analysis is distinct from an obviousness analysis. In other words, "a description that merely renders the invention obvious does not satisfy the requirement." *Ariad*, 598 F. 3d at 1352. To the contrary, "proof of priority requires written description disclosure in the parent application, not simply information and inferences drawn from uncited references." *L.A. Biomedical Rsch. Inst.*, 849 F.3d at 1058.

C. Anticipation

"Paramount among the patentability requirements is that that which is sought to be patented must be new." *In re Schoenwald*, 964 F.2d 1122, 1123 (Fed. Cir. 1992). Anticipation requires that every limitation recited in a claim be found in one item of prior art. *SRAM Corp. v. AD-II Eng'g, Inc.*, 367 F. App'x 150, 155 (Fed. Cir. 2010). As shorthand: that "which would literally infringe if later in time anticipates if earlier." *Upsher-Smith Labs v. Pamlab*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (calling this principle a "century-old axiom of patent law").

V. ARGUMENT

The Asserted Claims are anticipated by Ogitani, in which DSC publicly disclosed the structure of DS-8201—the product that Seagen accuses of infringement here. Seagen therefore has conceded, based on its analysis of DS-8201, that Ogitani satisfies every limitation of the Asserted Claims, which were not filed until three years after Ogitani was published. [redacted] Black letter patent law therefore dictates that Ogitani anticipates the Asserted Claims unless they are entitled to an earlier filing date.

As the rest of this motion demonstrates, the Asserted Claims *cannot* claim priority back to the applications Seagen filed in 2003 and 2004. There is no support for the claimed subgenus of Gly/Phe-only tetrapeptide linkers in the Priority Applications—there is *no* mention, explicit or implicit, of this category of linkers anywhere in them. And by the repeated, sworn admissions of Seagen's named inventors, Seagen had not even conceived of Gly/Phe-only tetrapeptide linkers as of 2003-2004, let alone described them in the Priority Applications.

The priority date of the '039 patent is therefore the filing date of the '839 Application, the first application to include Gly/Phe-only tetrapeptide linker claims: July 10, 2019. Seagen's assertion that DS-8201 falls within the scope of the Asserted Claims (necessary for Seagen to succeed in its infringement case) thus means that the Asserted Claims are anticipated by Ogitani.

A. The Asserted Claims are Invalid as Anticipated Unless Seagen Can Establish Priority to Earlier-Filed Applications.

The application that led to the '039 patent was filed on July 10, 2019. '039 patent, at 1. Seagen—consistent with its effort to prove infringement—argues that Ogitani, a 2016 publication

authored by Daiichi Sankyo Japan scientists about DS-8201, meets every limitation of the Asserted Claims of the '039 patent. In particular, Seagen's inventor and Vice President of Chemistry Dr. Peter Senter testified as a 30(b)(6) witness [redacted] In summary, Dr. Senter testified that [redacted] Seagen's sole validity expert, Dr. Bertozzi, [redacted]

Because that "which would literally infringe if later in time anticipates if earlier," *Upsher-Smith Labs*, 412 F.3d at 1322, Seagen's only defense against anticipation is to claim priority to applications filed in 2003 and 2004.

B. The '039 Patent Cannot Claim Priority to a Date Before 2019

Seagen asserts that the '039 patent is entitled to a priority date of no later than the 2004 Application's filing date: November 5, 2004. But the 2004 Application—like every application Seagen filed before July 10, 2019—lacks written description support for the Asserted Claims. Neither the 2004 application nor any other earlier-filed application described the claimed subgenus of Gly/Phe-Only tetrapeptide linkers recited in the Asserted Claims. Instead, Seagen's earlier-filed applications disclose broad categories of peptides with 2-12 amino acids, with the tetrapeptide category alone covering more than 47 million possible tetrapeptide linkers, and provide no legally-required "blaze marks" directing the POSA to the narrower subgenus of the tetrapeptide category

of linkers using only glycine or phenylalanine. Seagen has identified no evidence to the contrary. No such evidence exists.

1. The '340 Application's Disclosure of 47 Million Tetrapeptides Does Not Describe the Claimed Subgenus of *G/F-Only* Tetrapeptides

The parties agree that the "Amino Acid Unit" section of the Priority Applications discloses an enormous set of potential peptide linkers, and that this set does not *exclude* the 81 claimed, Gly/Phe-only tetrapeptides. Seagen argues this is enough. Bertozzi Rebuttal Rep. at ¶ 296-297. The Federal Circuit disagrees.

a. No Disputed Facts

The parties do not dispute a single material fact regarding the disclosure of the Priority Applications. For example, they are in heated agreement that the Priority Applications disclose a tetrapeptide category with more than 47 million tetrapeptide linkers. Seagen's 30(b)(6) witness, Dr. Senter, acknowledged that the specification covers 47,458,321 options of tetrapeptide linkers.[14] This astronomical number results from the 83 possible options of amino acids for each of the four positions in a tetrapeptide sequence provided by the specification and priority applications. [redacted]

The parties *also* agree that the '039 patent claims a minute subgenus of those 47 million linkers: the number of options for tetrapeptides in the claims is [redacted] And the parties agree [redacted]

[14] [redacted]

[redacted] And they agree that [redacted]

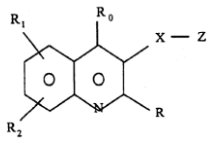
The parties *disagree* only as to the legal effect of these facts. Seagen argues that the claimed subgenus of Gly/Phe-only tetrapeptides is disclosed in the Priority Applications because it is contained somewhere within the vast disclosure of an unfathomably large number of peptide sequences. Seagen's sole validity expert, inventors, and 30(b)(6) witnesses repeatedly asserted that the claimed ADCs with Gly/Phe-only tetrapeptides are disclosed in the '039 patent and Priority Applications because they are included—along with a colossal number of other sequences—within the broad disclosure of different categories of peptide sequences of 2-12 amino acids, containing any of 83 choices at each position.[15] Seagen's priority argument is that its "laundry list" of peptide lengths and compositions at each position supports a written description of every sequence—including the Gly/Phe-only tetrapeptide sequences—within its scope. That argument is foreclosed as a matter of law. *Fujikawa*, 93 F.3d at 1571.

b. The 2003 Application's "Laundry List" of Amino Acids Is Not an *Ipsis Verbis* Description of Gly/Phe-Only Tetrapeptides

The Federal Circuit has held squarely that a "laundry list" disclosure of possible substituents at various positions in a chemical compound does *not* provide written description support for every possible combination of the listed elements. *Id.*

[15] [redacted]

In the seminal *Fujikawa* case, the Federal Circuit addressed an application that disclosed a chemical Markush group containing four variable "R" groups:



The application's disclosure specified multiple possible options for each R group. *Id.* at 1570 ("each of R and R_0 is, independently, C_{1-6} alkyl (primary, secondary, or tertiary), C_{3-7} alkyl, or [a depicted] ring [structure]" and "each of R_1, R_2, R_3, R_4, R_5 is, independently, hydrogen, C_{1-4}alkyl, C_{1-4}alkoxy, trifluoromethyl, fluoro, chloro, phenoxy, benzyloxy, or hydroxy"). The claim at issue specified that two of those R groups must take particular forms: "R is cyclopropyl and R_0 is 4-fluorophenyl." *Id.* at 1570 (footnotes omitted).

Even though both cyclopropyl (i.e., C_3 alkyl) and 4-fluorophenyl were *expressly listed* as options for R and R_0 in the application's disclosure, the Federal Circuit held that the claimed subgenus was "not disclosed *ipsis verbis* by the application." The Court explained its logic thus:

> [J]ust because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety. Were this the case, a 'laundry list' disclosure of every possible moiety for every possible position would constitute a written description of every species in the genus. This cannot be because such a disclosure would not 'reasonably lead' those skilled in the art to any particular species.

Id. at 1571. The same logic applies with equal force here: the Priority Applications disclose eleven categories of peptide linkers (dipeptides through dodecapeptides), with a laundry list of amino acids that can be used at any one of the two positions in a dipeptide, three positions in a tripeptide, or four positions in a tetrapeptide, and so on. Ex. 9 (2003 application), at SGIEDTX00000856-857; Ex. 10 (2004 application), at 86-87. Seagen claims only a tiny subset of one of those categories—the tetrapeptide category—containing only glycine and phenylalanine at each

position. This case therefore represents an extreme version of *Fujikawa*, where (unlike *Fujikawa*) the POSA must first select the category of peptide linkers (the number of R groups to be filled), and only then select from among the laundry list of amino acids to fill them to prepare peptide sequences.

That failure to claim an entire category disclosed in the priority application is precisely what distinguishes this case from *In re Driscoll*, 562 F.2d 1245 (C.C.P.A. 1977). There, the Court of Customs and Patent Appeals determined that a disclosure of fourteen categories of organic compounds provided adequate written support for a claim to one of those categories in its entirety. In *Driscoll*, "the exact subgenus claimed [was] clearly discernible in the generalized formula . . . set forth in the earlier filed application." *Id.* at 1250. Here, Seagen disclosed "tetrapeptides" as one of eleven categories of peptide linkers, but it claims a narrower, specific subset of that category—tetrapeptides containing only glycine and phenylalanine. That narrow category was *nowhere* described in the Priority Applications. The Federal Circuit has clarified that, while claiming an entire category of molecules disclosed in the specification potentially can satisfy the written description requirement, claiming only a subset of that category is legally inadequate. *See, e.g.*, *In re Wako Pure Chem. Indus., Ltd.*, 4 F. App'x 853, 857 (Fed. Cir. 2001) (holding that *Driscoll* does not apply, and the *Fujikawa* rule of failure to satisfy the written description requirement with a laundry list disclosure does apply, where the claim recited only a subset of one of the disclosed alternative structures or categories). The Priority Applications fit squarely within *Fujikawa's* rule, and lack support for Gly/Phe-only tetrapeptides.

In short, "something more than the disclosure of a class of 1000, or 100, or even 48 compounds is required" to claim a specific compound or subgenus of compounds. *Id.* at 856 (quoting *Ruschig*, 379 F.2d at 994). The Priority Applications do not disclose 48 compounds, a

number the Federal Circuit found too broad in *Ruschig*. 379 F.3d at 994. Instead, they disclose laundry lists of linkers that include nearly 48 *million* sequences in the tetrapeptide category alone. That broad, general disclosure cannot support a claim to the narrow subgenus of 81 Gly/Phe-only tetrapeptides without "something more", *id.*—i.e., without blaze marks that point the narrow claimed subgenus. No such blaze marks exist.

2. The Priority Applications Provide No Blaze Marks Leading to the Claimed Subgenus of Gly/Phe-Only tetrapeptides

In the absence of an *ipsis verbis* disclosure, a specification must disclose, within its four corners, "blaze marks" that would "provide[] adequate direction which reasonably would lead persons skilled in the art to the sub-genus of the [claim]." *Fujikawa*, 93 F.3d at 1570 (internal quotes omitted); *see also Ariad*, 598 F.3d at 1351; *FWP IP ApS*, 749 F. App'x at 974-77, & n.5; *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 2022 WL 16759, *5 (Fed. Cir. 2022) (a disclosure need not recite the claimed invention *in haec verba*, but a "laundry-list-type disclosure must provide blaze marks.").

a. The Preferred Embodiments and Examples Do Not Provide Blaze Marks to the Claimed Subgenus

The Priority Applications do not contain "blaze marks" that direct the POSA to the claimed subgenus. None of the preferred examples in the Priority Applications point toward the claimed subgenus of ADCs with *tetra*peptides containing *only* glycine and phenylalanine. The Priority Applications describe four "preferred" or "exemplary"[16] peptide linkers, but *none* are tetrapeptides: three are *di*peptides and one is a *tri*peptide. None of these contains only glycine and phenylalanine. Ex. 9 (2003 Application), at SGIEDTX00000858; Ex. 10 (2004 Application),

[16] The 2003 Application refers to these four linkers "preferred" whereas the 2004 Application describes these them as "exemplary" Amino Acid Units. Ex. 9 (2003 Application), at SGIEDTX00000858; Ex. 10 (2004 Application), at 87:4-8.

at 87:4-8. In fact, glycine is not included at *any* position in *any* of the preferred ADC examples. *Id.*[17]

None of the other non-"preferred" ADC examples in the Priority Applications fall within the scope of the claims or provide blaze marks in their direction either.

The Priority Applications disclose far more examples of dipeptides and tripeptides than of tetrapeptides—and none of the dipeptide and tripeptide examples are composed only of phenylalanine or glycine either. Ex. 10, at 86; [redacted] If the priority applications point the skilled artisan anywhere, it is toward the preferred shorter dipeptide and tripeptide linkers containing amino acids beyond phenylalanine and glycine, and away from the claimed subgenus of ADCs.

While not "preferred," the Priority Applications provide three examples of tetrapeptides from among the 47 million they disclose: (1) glycine-phenylalanine-leucine-glycine, (2) alanine-leucine-alanine-leucine, and (3) glycine-serine-valine-glutamine.[18] As is plain, *none* of these fall within the claimed subgenus of Gly/Phe-only tetrapeptides. Indeed, there is no dispute that the specification "fails to disclose even a single member of" the claimed subgenus. *Bos. Sci. Corp.*, 647 F.3d at 1367; [redacted]

Certainly, none of these examples "reasonably [would lead] persons skilled in the art' to the sub-genus of the [claim]." *Fujikawa*, 93 F.3d at 1570; *see also Bos. Sci. Corp.*, 647 F.3d at

[17] Phenylalanine is included as an amino acid in one each of the dipeptide and tripeptide examples, but no preferred example teaches it at the third or fourth position. Ex. 9 (2003 Application), at SGIEDTX00000858; Ex. 10 (2004 Application), at 87:4-8.

[18] The third example was added in the 2004 application and was not included in the 2003 Application. Ex. 10 (2004 Application), at 87:24; Ex. 9 (2003 Application), at SGIEDTX00000858.

1367-68 (holding that "no reasonable juror could determine that the specification reasonably conveys to persons skilled in the art that the inventor had possession of the claimed sub-genus" when the patent fails to indicate that the narrower, claimed sub-genus is of "special interest").

Indeed, this disclosure provides far *less* disclosure of the claimed subgenus than the one the Federal Circuit found wanting in *Fujikawa*. There, only two variable R groups were at issue—for one of them, R_0, the specification listed the claimed 4-fluorophenyl substituent as one of three preferred options for R_0. 93 F.3d at 1570. But, as the lower tribunal noted, the inventor "gave no indication in his application as to whether he would prefer any one of the choices over the other two." *Id.* And for the other variable group, R, the claimed cyclopropyl group was not listed as preferred. The Federal Circuit held that there were no requisite blaze marks, and thus no written description, where the recited "sub-genus diverges from [the application's] preferred elements." *Id.* at 1571. The same is true here, where, as a matter of undisputed fact, not a single species within the claimed subgenus (let alone the claimed subgenus, as required) is exemplified or otherwise identified in the priority applications, and the applications nowhere disclose that tetrapeptides—and certainly not the 81 Gly/Phe-only tetrapeptides of the claims—are preferred. Ex. 10 (2004 Application), at 87:4-8; Ex. 9 (2003 Application), at SGIEDTX00000858.

Fujikawa is just one of many cases standing for the proposition that real "blaze marks" are needed in order to support a claim directed to a specific subgenus. For example, in *Novozymes A/S v. DuPont Nutrition Bioscis. APS*, 723 F. 3d 1336, 1349 (Fed. Cir. 2013), the Federal Circuit found no written description where "one searches the [earlier] application in vain for the disclosure of even a single species that falls within the claims or for any "blaze marks" that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." And in *Boston Scientific Corp.*, 647 F. 3d at 1367, the Federal Circuit held the claim invalid for

lack of written description support as a matter of law where "the inventors . . . disclosed a genus (analogs of rapamycin), but claimed a narrower sub-genus (macrocyclic triene analogs of rapamycin)" and nothing "indicate[d] that the claimed triene analogs might be of special interest."). *See also Purdue Pharma*, 230 F.3d at 1326 (no written description of claims reciting extended-release formulation requiring a certain ratio between the drug's maximum plasma concentration and its concentration 24 hours after administration where "neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasize[d] the [claimed] ratio" and the POSA "would not be directed to the [claimed] ratio as an aspect of the invention.").

At bottom, the Priority Applications "simply describ[e] a large genus of compounds" which "is not sufficient to satisfy the written description requirement as to particular species or sub-genuses." *Fujikawa*, 93 F.3d at 1570-71.

b. Modification of the Examples Does Not Support the Claimed Subgenus

In addition to relying on the broad laundry list disclosure of the priority applications, Seagen argues that the POSA would have been motivated—by prior art and other information not disclosed in the Priority Applications— to modify the applciations' tetrapeptide examples or to create entirely new peptide sequences and thereby arrive at a subgenus that is *still not the claimed subgenus*. This argument conjures an image of Seagen, armed with a machete, attempting to forge a new and different path through the metaphorical forest than the one the application has marked—and ultimately not arriving at the claimed set of "trees" in any event. These theories are defective as a matter of law. The Federal Circuit uniformly has required that blaze marks lead to the claimed invention, not to unclaimed subgenera.

1) Seagen's written description analysis is legally flawed

Seagen's written description case rises and falls with the disclosure of the Priority Applications—not the manner in which the POSA might modify their disclosure in light of the prior art. "[I]t is not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to the modifications that the inventor might have envisioned, but failed to disclose." *D Three Enterprises, LLC v. SunModo Corp*., 890 F.3d 1042, 1050 (Fed. Cir. 2018) (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)) (both cases affirming summary judgment of anticipation because parent application lacked written description support for later claims); *L.A. Biomedical Rsch. Inst.*, 849 F.3d at 1058 (rejecting written description theory that would "at best require persons of skill to look to the prior art and make assumptions. That is not enough to establish priority."). In other words, "a description that merely renders the invention obvious does not satisfy the [written description] requirement." *Ariad*, 598 F. 3d at 1352.

Indeed, modifying the disclosure based on prior art often relies on impermissible hindsight. A proper written description analysis may not "'[w]ork[] backward from a knowledge of [the claims]'" in hopes of finding a path to the available disclosure. *Novozymes*, 723 F. 3d at 1349 (quoting *Ruschig*, 379 F.2d at 995). As the Federal Circuit has explained, once the POSA knows the claimed destination, "it is all very clear what route one would travel through the forest of the specification to arrive" there. *Id.* That is not a proper written description analysis. Instead, the proper inquiry must "view[] the matter from the proper vantage point "of one with no foreknowledge of the specific [later claims]." *Id.* (quoting *Ruschig*, 379 F.2d at 995).

In *Fujikawa*, for example, the appellant argued that the claimed subgenus required a substituent at position R that was not listed as preferred, but that the skilled artisan would have

been "moved" to substitute for one listed as preferred. *Fujikawa*, 93 F.3d at 1571. The Court explained that such observations may "seem simple" in "hindsight," but the disclosure itself did not suggest that substitution at that position. *Id.* To continue the forest analogy,

> [I]t is easy to bypass a tree in the forest, even one that lies close to the trail, unless the point at which one must leave the trail to find the tree is well marked. [The specification's] preferred embodiments do blaze a trail through the forest; one that runs close by [the claimed] tree. [The specification], however, does not direct one to the proposed tree in particular, and does not teach the point at which one should leave the trail to find it.

Id.; *Ariad*, 598 F. 3d at 1351-52 ("[I]t is the specification itself that must demonstrate possession."); *Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1342 (Fed. Cir. 2021).

In this case, there is no genuine dispute that the subgenus of 81 claimed trees are not on the trail blazed by the Priority Application's preferred embodiments or examples. And unlike in *Fujikawa*, the trail the Priority Applications' preferred embodiments and examples blaze does *not* run anywhere close to the claimed trees. Instead, the trail blazed by the Priority Applications cuts through a forest consisting principally of di-and tri-peptides. To the extent that trail intersects the wilderness of the separate category of 47 million-plus tetrapeptides, it takes only a glancing turn by the three tetrapeptides the specification exemplifies, none of which falls within the claimed subsection of 81 trees. Certainly, no guideposts within the Priority Applications direct the POSA to the web of unmarked paths that would arrive at the claimed subgenus. To the extent Seagen turns to the prior art to fill those gaps, Seagen "cannot rely on standalone references that it failed to incorporate in the provisional application in order to make out its priority claim. . . '[I]t is the disclosures of the [provisional] application[ ] that count,' not those of uncited references." *L.A. Biomedical Rsch. Inst.*, 849 F.3d at 1058 (internal quotes omitted).

2) Seagen identifies "blaze marks" to the wrong subgenus

Crucially for purposes of this motion, even assuming Seagen's arguments about modifying

the tetrapeptide examples were legally permissible, Seagen's blaze marks theories still fail as a matter of law. That is because the named inventors and Seagen's expert *agree* that if the POSA were motivated to modify the tetrapeptide examples in the Priority Applications in the manner they propose, the POSA would arrive a subgenus of tetrapeptides that is *not* the one claimed. *See* Section III.A.3.

Dr. Bertozzi identified [redacted] Seagen's inventors identified a [redacted] *None* of these subgenera are the one Seagen claimed: 81 tetrapeptides that contain *only* glycine and phenylalanine. It did *not* claim a motley assortment of tetrapeptides and tripeptides that happen to include a handful of the 81 claimed Gly/Phe-only tetrapeptides, along with various other peptides outside the claims. It claimed a particular set of 81 tetrapeptides with a clear defining principle: the only amino acids would be glycine and phenylalanine. Seagen's hindsight-guided path does not arrive there.[19]

[19] Seagen has not even tried to obscure that the blaze marks it identifies, based on information outside the priority applications, were drawn in hindsight and thus legally improper. *Supra* Section V.IB.2.b.1. Dr. Doronina admitted that [redacted]

As a matter of law, Seagen's effort to establish written description through blaze marks necessarily fails. In the end, this case is on all fours with *Fujikawa*. Here, as there, "the compounds of the [Asserted Claims] were not [the inventor's] preferred, and . . . [the] application contained no blazemarks as to what compounds, other than those disclosed as preferred, might be of special interest." *Fujikawa*, 93 F.3d at 1571. *See also Bos. Sci. Corp.*, 647 F.3d at 1367 (holding, as a matter of law, that the specification failed to adequately describe the claims in the absence of blazemarks). The result must be the same. The Priority Applications do not provide written description support for the Asserted Claims.

3. Seagen's Named Inventors Admit That They Did Not Have Possession of Nor Provide Blazemarks to the Claimed Subgenus

The issue presented by this motion is open and shut for another reason. The inventors admit that they were not, in fact, in possession of the claimed subgenus any time before DS-8201 was published by Daiichi Sankyo in 2016. So it is no coincidence that the Priority Applications do not describe the claimed subgenus. Indeed, the inventors themselves admit that the Priority Applications do not have blaze marks directing to the claimed subgenus.

Dr. Senter, Seagen's corporate designee regarding the conception and reduction to practice of the Asserted Claims, was asked the following: [redacted]

[redacted]

[redacted]

Seagen desperately (and impermissibly) attempts to modify this particular sworn answer via

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[redacted] The inventors agreed that [redacted] and therefore could not have described the invention in the 2004 application as a matter of law. *Falkner*, 448 F.3d at 1367 n.13 ("[O]ne cannot describe what one has not conceived.").

errata.[20] But that is beside the point, as Dr. Senter admitted the lack of written description support repeatedly. For example, Dr. Senter was asked [redacted] That answer likewise precludes any finding that his 2003 and 2004 applications described the subgenus and resolves this case as a matter of law. And there is more. Dr. Senter was asked [redacted]

[20] Dr. Senter's sworn answer so thoroughly demolishes Seagen's case that the Plaintiff has resorted to submitting demonstratively false errata, violating clear precedent that "attorneys may not use an errata sheet to push a case to trial where the client no longer adheres to the allegations supporting the claim." *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 480 (5th Cir. 2012). In a December 17, 2021 errata sheet, the response was doctored to read, [redacted] Seagen's revision of its 30(b)(6) testimony proposes an illogical response to the question, which did not ask about the breadth of the disclosure at all, but rather whether the application provided blaze marks. Even if credited, it does not create a factual issue, as even in the take-home exam version of the deposition, Dr. Senter does not assert [redacted] Nevertheless, Dr. Senter's errata should be disregarded by the court under the "sham-affidavit" doctrine. *See Devon Energy Corp. v. Westacott*, 2011 WL 1157334, *6 (S.D. Tex. Mar. 24, 2011) (only permitting contrary errata "if sufficiently persuasive reasons are given, if the proposed amendments truly reflect the deponent's original testimony, or if other circumstances satisfy the court that amendment should be permitted" (quoting *EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 270 (3d Cir. 2010))); *see also Burns v. Board of County Comm. of Jackson County*, 330 F.3d 1275, 1282 (10th Cir. 2003) ("We will disregard a contrary affidavit, however, when it 'constitutes an attempt to create a sham fact issue.'" (quoting *Franks v. Nimmo*, 796 F.2d 1230, 1237 (10th Cir. 1986))).

[redacted]

Named inventor Toni Beth Kline also confirmed that the Priority Applications do not contain blaze marks directing to the claimed subgenus. She testified as follows:

[redacted]

[redacted] But it is not enough that she [redacted] — the Priority Applications must provide blaze marks pointing to them. *Bos. Sci. Corp*, 647 F.3d at 1367. They did not.

Similarly, Dr. Doronina, another Seagen inventor and longtime Seagen scientist, testified [redacted] This, too, is case dispositive: A [redacted] is legally insufficient to satisfy the written description requirement. *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926-27 (Fed. Cir. 2004); *Bos. Sci. Corp.*, 647 F.3d at 1367 ("The patent laws do not reward an inventor's invitation to other researchers to discover" the claimed peptide sequences.). A specification must "teach the specific compound" to fulfill its part of the "*quid pro quo* in which the public is given

[21] Later in his deposition, Dr. Senter [redacted] *supra* Section III.A.4. That is, Dr. Senter believed [redacted] Regardless, Drs. Senter and Doronina [redacted]

meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." *Univ. of Rochester*, 358 F.3d at 922 (quotations omitted).

This testimony from Seagen's corporate designee, along with that of other inventors, sets this case apart. Many cases involve complex, competing claims of invention. This one does not. Here, the inventors readily admitted—repeatedly and under oath—that they had not conceived of, and therefore could not have described, the subgenus of ADCs with Gly/Phe-only tetrapeptides when they filed their Priority Applications. In fact, Dr. Senter admitted [redacted] Because, as a matter of logic and law, "one cannot describe what one has not conceived," *Falkner*, 448 F.3d at 1367 n.13 (quoting *Fiers*, 984 F.2d at 1171), the repeated acknowledgement of Seagen's inventors that they had not thought of the idea of Gly/Phe-only tetrapeptides in 2004 provides yet another independent reason Seagen's priority claim cannot succeed. *Supra* Section III.A.4.

VI. CONCLUSION

The importance of the written description requirement is at its zenith when, as here, a patentee added claims in response to the discovery of others. Seagen's own corporate-designee and inventor dutifully walked through the Asserted Claims of the '039 patent to demonstrate that every limitation was met by his understanding of Daiichi Sankyo Japan's 2016 publication of DS-8201 in Ogitani. Seagen's expert agrees. Seagen's own witnesses have admitted that the Priority Applications fail to demonstrate they possessed the '039's claimed subgenus of ADCs with certain tetrapeptides, as the written description doctrine requires. This makes sense, because Seagen had not conceived of the later-claimed subgenus by 2004, and thus could not have described it. The Court should grant the Defendant's motion for summary judgment.

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Respectfully submitted,

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(with permission by Jennifer P. Ainsworth)

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document was filed electronically UNDER SEAL and served by e-mail on January 6, 2022, to all counsel of record.

/s/ Jennifer P. Ainsworth
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